PCT

WORLD INTELLECTUAL PROPERTY ORGANIZATION International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 5: (11) International Publication Number: A1 A61F 5/10

WO 94/20049

(43) International Publication Date: 15 September 1994 (15.09.94)

PCT/AU94/00105 (21) International Application Number:

(22) International Filing Date: 8 March 1994 (08.03.94)

(30) Priority Data:

PL 7671 8 March 1993 (08.03.93) AU PL 9155 2 June 1993 (02.06.93) ΑU PM 1018 6 September 1993 (06.09.93) ΑÜ

(71) Applicant (for all designated States except US): FINGEASE PTY. LTD. [AU/AU]; 17 The Tor Walk, Castlecrag, NSW 2068 (AU).

(72) Inventor; and

(75) Inventor/Applicant (for US only): O'KEEFFE, Paul, John [AU/AU]; 17 The Tor Walk, Castlecrag, NSW 2068 (AU).

(74) Agent: O'KEEFFE, Paul, John; P.O. Box 654, Brookvale, NSW 2100 (AU).

(81) Designated States: AU, GB, US.

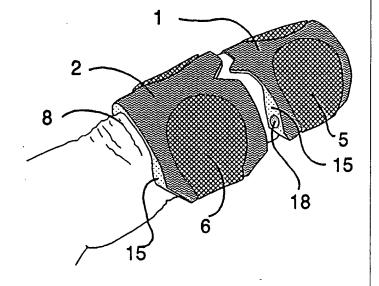
Published

With international search report. With amended claims.

(54) Title: DYNAMIC TRACTION SPLINT

(57) Abstract

A therapeutic dynamic traction splint for treatment of osteoarthritis of interphalangeal joints of a digit comprises two phalanx-gripping means (1, 2) which are biased apart by means of magnetic repulsion (18) or spring tension. The phalanx-gripping means (1, 2) provides sufficient traction to stretch collateral ligaments in the full joint range of movement by aligning magnet poles or spring pivots to the axis of joint movement. When magnets are used they are arranged to produce rotational stability of the splint. The splint delivers traction force to the phalanx and avoids a torniquet effect by applying pressure to the sides of the digit (15). The bands are cut away on the volar aspect of the digit to allow full and free joint movement during treatment.



FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	GB	United Kingdom	MR	Mauritania
ΑÜ	Australia	GE	Georgia	MW	Malawi
BB	Barbados	GN	Guinea	NE	Niger
BE	Belgium	GR	Greece	NL	Netherlands
BF	Burkina Faso	HU	Hungary	NO	Norway
BG	Bulgaria	IE.	Ireland	NZ	New Zealand
BJ	Benin	īī	Italy	PL	Poland
BR	Brazil	JP	Japan	PT	
BY	Belarus	KE	Kcoya	RO	Portugal
CA	Canada	KG			Romania
CF	Central African Republic	KP	Kyrgystan	RU	Russian Federation
CG	Congo	ы	Democratic People's Republic	SD	Sudan
	Switzerland	****	of Korea	SE	Sweden
CH		KR	Republic of Korea	SI	Slovenia
CI	Côte d'Ivoire	KZ	Kazakhstan	SK	Slovakia
CM	Cameroon	П	Liechtenstein	SN	Senegal
CN	China	LK	Sri Lanka	TD	Chad
cs	Czechoslovakia	LU	Luxembourg	TG	Togo
CZ	Czech Republic	LV	Latvia	TJ	Tajikistan
DE	Germany	MC	Мовасо	TT	Trinidad and Tobago
DK	Denmark	MD	Republic of Moldova	ÜA	Ukraine
ES	Spain	MG	Madagascar	US	United States of America
FI	Finland	ML	Mali	UZ	Uzbekistan
FR	France	MIN	Mongolia	VN	Vict Nam
GA	Gehon			***	* *** * * ******

WO 94/20049 PCT/AU94/00105

Dynamic traction splint

This invention is a splint for treatment of osteoarthritis of the finger. When used it reduces the pressure within the joint and alleviates pain. It may also reverse the progress of the disease by correcting joint contractures and allowing new articular cartilage to form.

The conventional explanation for osteoarthritis is the presence of an inferior quality articular cartilage which wears faster than normal cartilage. The range of joint movement may be reduced leading to fixed flexion deformity and bony outgrowths may occur (Hebeden's nodes) leading to cosmetic deformity.

The inventor is a plastic surgeon and he has an alternate view of the cause of osteoarthritis. Fibrous tissue contractures are commonly seen by plastic surgeons who are also aware that the elastic tissue component of fibrous tissue decreases with ageing. It is conceivable that osteoarthritis is also caused by increased stress on normal cartilage due to contracture and/or reduced elastic complience of the collateral ligamaents. Increased joint pressure could damage the cartilage and cause wear.

Stretching the collateral ligaments should relieve the stress on the cartilage and reduce joint pressure. This should reduce arthritic pain and further joint damage. Joint range may increase thereby reducing the extent of any fixed flexion deformities. Further stretching of the collateral ligaments would cause joint distraction and create a space at the joint surfaces. New cartilage might form to partially replace eroded cartilage if the joint is actively flexed and extended during traction since it is known that chronic movement at a fracture site can lead to non-union and pseudarthrosis formation.

Stretching a ligament is not easily accomplished because pulling on a ligament may not necessarily stretch it. For instance, when a muscle pulls on a tendon during exercise the intermittent pulls may strengthen the tendon. Since tendons and ligaments have a similar structure, pulling intermittently on a finger may strengthen the ligaments of the interphalangeal joints rather than stretch them. By contrast, prolonged gentle traction, strong enough to stretch a ligament, would be more likely to stretch the ligaments and be less likely to strengthen them.

To review the prior art a search of medical literature was made and rheumatologists were consulted. No reference was found citing ligament contracture or reduced elastic complience of ligaments as a cause of osteoarthritis in fingers or toes. No therapy directed towards stretching collateral ligaments in fingers or toes was discovered so it is highly unlikely that prior art devices for such therapy exist. The device of Donohue, US, A, 5020524 4 June 1991 (04.06.91), is not satisfactory because it does not allow free joint movement, it is unsafe for prolonged application due to the risk of a torniquet effect from the digit-encircling bandages and if fixed to the skin with adhesive it may merely stretch the skin and not the collateral ligaments.

Design principles took into account the necessity for freedom of joint movement, avoidence of a torniquet effect which could interfere with blood circulation to the finger if the splint is to remain in place over night, the necessity for the applied force to act on the skeleton rather than just on the skin and maintenance of the stretching force in line with the collateral ligament whether the joint is extended or flexed.

To allow freedom of joint movement during the ligament stretching process the device consists of two separate bands, one for attaching to the finger segment (1) distal to the joint being treated and the other for attaching to the segment (2) proximal to the joint. To allow full flexion of the finger the band should not obstruct apposition of the skin on the volar aspect (3) of the interphalangeal joints. Therefore, the band should be open on the volar side (4) or any part of the band which bears on the volar side of the finger should be narrow and bear on the middle of the finger segment only.

The band would be hazardous if it could be applied with undue pressure on the veins of the digit which lie on the dorsum of the digit. The veins are low pressure vessels and very little pressure is required to obstruct them. When veins are obstructed blood may continue to flow into the digit via the arteries and swelling occurs. This results in increasing pressure within the digit until the pressure equals the arterial pressure where upon circulation ceases and tissue damage may occur.

Finger vascularity will be safer if the band exerts pressure from side to side rather than circumferentially. A flexible band (1,2) which is open on the volar side (4) and which has thicker padding (15) for the sides of the digit and thinner padding (8) for the dorsum of the digit roughly conforms an to elliptical shape when fitted to the finger with strapping (5,6). The long axis of the ellipse (7) is transverse so the radius of curvature is smallest on the sides of the finger. Therefore, according to Laplace, the tissue pressure exerted by the band and strapping is higher on the sides than on the dorsal and volar parts of the finger.

The objective of the device is to produce tension in the collateral ligaments (9) and so the applied traction must act upon the skeleton (10,11). Traction applied directly to the skin may be partly dissipated within the skin. This splint is designed to apply traction to the distal phalanx via the nail (12) which is firmly adherent to the bone and to apply traction to the middle or proximal phalanges by virtue of the waisted lateral profile of these bones, applying pressure where the bone width is increasing (13).

The nail (12) is hard and spreads the skin and soft tissue of the finger forming lateral nail folds. The folds are relatively small so the band effectively grips the nail on its sides via the lateral skin folds.

3

The width (14) of the band for the middle or proximal segment should be less than the length of the phalanx. Thus when the band is applied to the finger the edge of the band away from the joint being treated pushes against the junction between shaft and base of the phalanx (13). The consistency of the band (1, 2) should be flexible but non-distensible and the consistency of any padding (15) lining the band should be such that it resists undue compression at this pressure point. Felt, polyurethane foam or sponge rubber are suitable padding materials.

The ligament-stretching force must act regardless of the degree of joint flexion because different portions of the ligament will be stretched at different degrees of joint flexion. This will be so if the force pivotally acts upon the band corresponding to the proximal attachment (16) of the collateral ligament (9). The surface marking of the centre of the proximal attachment of a collateral ligament, that is, the axis of rotation (16) of the joint, is the dorsal extremity of the intersegmental volar skin crease (17) on the side of the finger.

Springs or pairs of magnets (18) arranged to repel have been used to produce the ligament-stretching force in prototypes. It is conceivable that cams, pneumatic means and hydraulic means could also be used. Springs have been V-shaped, forcing open after activating by closing the V. Other spring configurations could be used. Magnets are preferred because the bands can then be totally separate allowing the greatest freedom of joint movement.

Magnetic rods (18) made from Neodymium-iron-boron with poles at the ends have been used in prototypes. Curved on the flat rectangular plates with poles at the ends are proposed for this device but have not yet been made. The magnets (18) are attached to or embedded in the band (1,2) or padding (15). The magnets are placed such that the proximal repelling magnetic pole will be on the axis of rotation (16) of the joint (17).

The magnetic repulsion force can produce rotational instability of the bands when applied to a finger. This is represented schematically in Figure 7 wherein 19 is the distal band, 20 is the proximal band, 21 is the usable magnetic force for traction and 22 is an example of the magnetic force causing relative rotation of the bands. Rotational stability is produced if the magnetic axes of the magnets on one band are "inside" the magnetic axes of the magnets on the other band. This is represented schematically in Figure 8 wherein 23 is the stabilising magnetic force. Any rotation of one band away from correct alignment moves one of the magnets closer to its opposing magnet and increases the force of repulsion which corrects the misalignment. Improved rotational stability is produced if six magnets are used, three on each side of the digit. This is represented schematically in Figure 9. One magnet is then acting against the like poles of two magnets which are arranged parallel with a space between. The single magnet maintains its position with its magnetic axis between the magnetic axes of the magnet pair.

WO 94/20049 PCT/AU94/00105

4

THE PREFERRED EMBODIMENT

Figure 1 shows the preferred embodiment of the invention in which the bands (1, 2) are made from Velcro loop material and the reusable releasable straps (5,6) are made from Velcro hook material. The padding (15) is made from foamed polyurethane or similar mouldable material, moulded so that the padding for the sides of the digit will be relatively thick and the padding for the dorsum of the finger will be relatively thin. Six neodymium-iron-boron rod magnets (18) magnetised in the long axis are embedded in the padding (15), three for each side of the digit. One magnet is embedd on each side of the padding for the distal of the two digital segments and two magnets are embedded in the padding for the proximal of the two digital segments. The magnets are arranged so that their like poles repel. The paired magnets in side of the proximal padding are arranged in parallel with a gap sufficient for the single magnet to be always repelled and tend to remain between the axes of the two magnets. If the magnets are two widely placed the single magnet may not be repelled when it is close to the two magnets. If the magnets are too close together they produce a magnetic field as if they were a single magnet and lateral stability is lost, the single magnet tending to move away from the magnetic axis of the two magnets.

Figure 4 shows a cross-section of the proximal band and padding of the preferred embdiment of the invention. The strap (6) is smoothed where it comes in contact with the volar skin with a layer of embedded silicone elastomer (24).

·5

FIGURES

Oblique view of dynamic traction splint on a finger. Figure 1: Figure 2: Side view of dynamic traction splint on a finger. Figure 3: Dorsal view of dynamic traction splint on a finger. Figure 4: Cross-section of the splint. Figure 5: Lateral view of two phalanges. Figure 6: Horizontal section of dynamic traction splint on a finger. Schematic representation of dynamic traction splint with coaxially arranged Figure 7: magnets. Figure 8: Schematic representation of dynamic traction splint with proximal magnets arranged with magnetic axes "inside" the magnetic axes of the distal magnets. Figure 9: Schematic representation of dynamic traction splint with the magnetic axis of each single distal magnet between the magnetic axes of the corresponding paired proximal magnets.

6

CLAIMS

- I. A dynamic traction splint which can be safely worn overnight to treat an osteoarthritic interphalangeal joint of a digit, comprising:
 - A. a first phalanx-gripping means for gripping a first phalanx, said first phalanx being immediately proximal to said interphalangeal joint, said first phalanx-gripping means gripping said first phalanx substantially by pressing on the sides of said digit near the junction between the shaft and base of said phalanx thereby avoiding a torniquet effect on blood circulation,
 - B. a second phalanx-gripping means for gripping a second phalanx, said second phalanx being immediately distal to said interphalangeal joint, said second phalanx-gripping means gripping said second phalanx substantially by pressing on the sides of said digit near the junction between the shaft and base of said phalanx thereby avoiding a torniquet effect on blood circulation and
 - C. a means for biasing the two said phalanx-gripping means apart thereby imparting a stretching force on the ligaments of said interphalangeal joint.
- II. The dynamic traction splint of Claim I wherein said means for biasing the two said phalanx-gripping means apart consists of a plurality of magnets and wherein:
 - A. said magnets are arranged to produce a magnetic repulsion force and
 - B. said magnets are attached to, or incorporated in, the two said phalanx-gripping means.
- III. The dynamic traction splint of Claim II wherein said plurality of magnets consists of four magnets arranged as two pairs and wherein:
 - A. one said pair is on each side of said digit and
 - B. the respective magnets of said first phalanx-gripping means are positioned so their respective repellent magnetic poles are as close as possible to the axis of rotation of said interphalangeal joint thereby causing said magnetic repulsion force to be constant regardless of the degree of flexion of said interphalangeal joint.

- IV. The dynamic traction splint of Claim II wherein said plurality of magnets consists of six magnets arranged as two groups of three magnets each and wherein:
 - A. one said group is on each side of said digit,
 - B. said group is arranged as a pair of magnets spaced apart repelling one magnet thereby improving rotational stability of the two said phalanx-gripping means around said digit and
 - C. the magnet, or magnets, of said first phalanx-gripping means are positioned so their respective repellent magnetic poles are collectively as close as possible to the axis of rotation of said interphalangeal joint thereby causing said magnetic repulsion force to be constant regardless of the degree of flexion of said interphalangeal joint.
- V. The dynamic traction splint of Claim I wherein said means for biasing the two said phalanx-gripping means apart consists of two compressed springs and wherein:
 - A. said springs are pivotally and removably attached on each sides of the two said phalanx-gripping means and
 - B. said spring attachments to said first phalanx-gripping means are as close as possible to the axis of rotation of said interphalangeal joint thereby causing said biasing force to be constant regardless of the degree of flexion of said interphalangeal joint.
- VI. The dynamic traction splint of Claim I wherein said phalanx-gripping means partially envelops said digit leaving the volar surface of said digit uncovered thereby allowing full flexion of said interphalangeal joint.
- VII. The dynamic traction splint of Claim I wherein said phalanx-gripping means is custom-molded from a thermoplastic splint material and molded directly on said digit.
- VIII. The dynamic traction splint of Claim I wherein said phalanx-gripping means is made from a rigid polymer and wherein
 - A. said rigid polymer is cut longitudinally into halves for ease of fitting to said digit and
 - B. said halves are fastened together on said digit.

- IX. The dynamic traction splint of Claim I wherein said phalanx-gripping means is made from a springy solid material and wherein:
 - A. said springy solid material may be opened up for application to said digit.
- X. The dynamic traction splint of Claim I wherein said phalanx-gripping means comprises:
 - A. an outer layer of non-distensible flexible fabric,
 - B. an inner layer of substantially firm but resilient padding, said padding being thicker at the sides of said digit and thinner over the dorsum of said digit thereby substantially increasing pressure at said sides and lessening pressure on the dorsum of said digit thereby preventing a torniquet effect on blood circulation and
 - C. a strapping for retaining said phalanx-gripping means on said digit being releasably attached to the sides of said outer layer.
- XI. The phalanx-gripping means of Claim X wherein:
 - A. said outer layer consists of Velcro loop fabric and
 - B. said strapping consists of Velcro hook fabric.
- XII. A dynamic traction splint which can be safely worn overnight to treat an osteoarthritic distal interphalangeal joint of a digit, said digit having an intact nail firmly attached to the distal phalanx of said digit, comprising:
 - A. a means for gripping the middle phalanx of said digit which grips said middle phalanx by substantially pressing on the sides of the digit near the junction between the shaft and base of said phalanx thereby avoiding a torniquet effect on blood circulation,
 - B. a means for gripping said nail by substantially pressing onto the external surface of said nail and onto the volar surface of the distal segment of said digit thereby avoiding a torniquet effect on blood circulation and
 - C. a means for biasing apart the two phalanx gripping means thereby imparting a stretching force on the ligaments of the said interphalangeal joint.

- XIII. The dynamic tracion splint of Claim XII wherein said means for biasing the two said phalanx-gripping means apart consists of a plurality of magnets and wherein:
 - A. said magnets are arranged to produce a magnetic repulsion force and
 - B. said magnets are attached to, or incorporated in, the two said phalanx-gripping means.
- XIV. The dynamic traction splint of Claim XIII wherein said plurality of magnets consists of four magnets arranged as two pairs and wherein:
 - A. one said pair is on each side of said digit and
 - B. the respective magnets of said first phalanx-gripping means are positioned so their respective repellent magnetic poles are as close as possible to the axis of rotation of said interphalangeal joint thereby causing said magnetic repulsion force to be constant regardless of the degree of flexion of said interphalangeal joint.
- XV. The dynamic traction splint of Claim XIII wherein said plurality of magnets consists of six magnets arranged as two groups of three magnets each and wherein:
 - A. one said group is on each side of said digit,
 - B. said group is arranged as a pair of magnets spaced apart repelling one magnet thereby improving rotational stability of the two said phalanx-gripping means around said digit and
 - C. the magnet, or magnets, of said first phalanx-gripping means are positioned so their respective repellent magnetic poles are collectively as close as possible to the axis of rotation of said interphalangeal joint thereby causing said magnetic repulsion force to be constant regardless of the degree of flexion of said interphalangeal joint.

- XVI. The dynamic traction splint of Claim XII wherein said means for biasing the two said phalanx-gripping means apart consists of two compressed springs and wherein:
 - A. said springs are pivotally and removably attached on each sides of the two said phalanx-gripping means and
 - B. said spring attachments to said first phalanx-gripping means are as close as possible to the axis of rotation of said interphalangeal joint thereby causing said biasing force to be constant regardless of the degree of flexion of said interphalangeal joint.
- XVII. A method for treating osteoarthritis of an interphalangeal joint of a digit comprising the steps of:
 - A. applying a predetermined traction force to the collateral ligaments of said interphalangeal joint with a dynamic taction splint,
 - B. applying said traction force for an interval of between five minutes and twelve hours,
 - C. vigorously flexing and extending said interphalangeal joint for a period of at least five minutes after said interval,
 - D. removing said dynamic traction splint and
 - E. repeating said treatment steps on a regular basis until symptoms of joint pain and stiffness are improved.

J

11

AMENDED CLAIMS

[received by the International Bureau on 24 May 1994 (24.05.94); original claims 1, 5, 11, 16 and 17 amended; other claims unchanged (6 pages)]

- 1. A dynamic traction splint which can be safely worn overnight to treat an osteoarthritic interphalangeal joint of a digit, comprising:
 - a. a first phalanx-gripping means for gripping a first phalanx, said first phalanx being immediately proximal to said interphalangeal joint, said first phalanx-gripping means gripping said first phalanx substantially by pressing on the sides of said digit near the junction between the shaft and base of said phalanx thereby avoiding a torniquet effect on blood circulation,
 - b. a second phalanx-gripping means for gripping a second phalanx, said second phalanx being immediately distal to said interphalangeal joint, said second phalanx-gripping means gripping said second phalanx substantially by pressing on the sides of said digit near the junction between the shaft and head of said phalanx thereby avoiding a torniquet effect on blood circulation and
 - c. a means for biasing the two said phalanx-gripping means apart thereby imparting a stretching force on the ligaments of said interphalangeal joint.
- 2. The dynamic traction splint of Claim 1 wherein said means for biasing the two said phalanx-gripping means apart consists of a plurality of magnets and wherein:
 - a. said magnets are arranged to produce a magnetic repulsion force and
 - b. said magnets are attached to, or incorporated in, the two said phalanx-gripping means.
- 3. The dynamic traction splint of Claim 2 wherein said plurality of magnets consists of four magnets arranged as two pairs and wherein:
 - a. one said pair is on each side of said digit and

- b. the respective magnets of said first phalanx-gripping means are positioned so their respective repellent magnetic poles are as close as possible to the axis of rotation of said interphalangeal joint thereby causing said magnetic repulsion force to be constant regardless of the degree of flexion of said interphalangeal joint.
- 4. The dynamic traction splint of Claim 2 wherein said plurality of magnets consists of six magnets arranged as two groups of three magnets each and wherein:
 - a. one said group is on each side of said digit,
 - b. said group is arranged as a pair of magnets spaced apart repelling one magnet thereby improving rotational stability of the two said phalanx-gripping means around said digit and
 - c. the magnet, or magnets, of said first phalanx-gripping means are positioned so their respective repellent magnetic poles are collectively as close as possible to the axis of rotation of said interphalangeal joint thereby causing said magnetic repulsion force to be constant regardless of the degree of flexion of said interphalangeal joint.
- 5. The dynamic traction splint of Claim 1 wherein said means for biasing the two said phalanx-gripping means apart consists of two compressed springs and wherein:
 - a. said springs are pivotally and removably attached on each side of the two said phalanx-gripping means and
 - b. said spring attachments to said first phalanx-gripping means are as close as possible to the axis of rotation of said interphalangeal joint thereby causing said biasing force to be constant regardless of the degree of flexion of said interphalangeal joint.
- 6. The dynamic traction splint of Claim 1 wherein said phalanx-gripping means partially

envelops said digit leaving the volar surface of said digit uncovered thereby allowing full flexion of said interphalangeal joint.

- 7. The dynamic traction splint of Claim 1 wherein said phalanx-gripping means is custom-molded from a thermoplastic splint material and molded directly on said digit.
- 8. The dynamic traction splint of Claim 1 wherein said phalanx-gripping means is made from a rigid polymer and wherein
 - a. said rigid polymer is cut longitudinally into halves for ease of fitting to said digit and
 - b. said halves are fastened together on said digit.
- 9. The dynamic traction splint of Claim 1 wherein said phalanx-gripping means is made from a springy solid material and wherein:
 - a. said springy solid material may be opened up for application to said digit.
- 10. The dynamic traction splint of Claim 1 wherein said phalanx-gripping means comprises:
 - a. an outer layer of non-distensible flexible fabric,
 - b. an inner layer of substantially firm but resilient padding, said padding being thicker at the sides of said digit and thinner over the dorsum of said digit thereby substantially increasing pressure at said sides and lessening pressure on the dorsum of said digit thereby preventing a torniquet effect on blood circulation and
 - c. a strapping for retaining said phalanx-gripping means on said digit being releasably attached to the sides of said outer layer.

11. The dynamic traction splint of Claim 10 wherein:

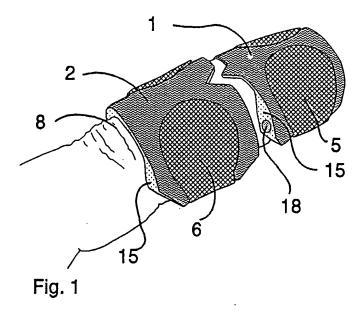
WO 94/20049

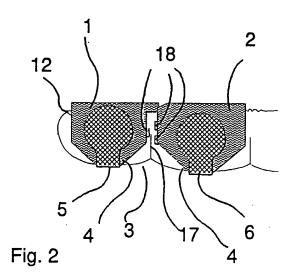
- a. said outer layer of said phalanx-gripping means consists of Velcro loop fabric and
- b. said strapping of said phalanx-gripping means consists of Velcro hook fabric.
- 12. A dynamic traction splint which can be safely worn overnight to treat an osteoarthritic distal interphalangeal joint of a digit, said digit having an intact nail firmly attached to the distal phalanx of said digit, comprising:
 - a. a means for gripping the middle phalanx of said digit which grips said middle phalanx by substantially pressing on the sides of the digit near the junction between the shaft and base of said phalanx thereby avoiding a torniquet effect on blood circulation,
 - b. a means for gripping said nail by substantially pressing onto the external surface of said nail and onto the volar surface of the distal segment of said digit thereby avoiding a torniquet effect on blood circulation and
 - c. a means for biasing apart the two phalanx gripping means thereby imparting a stretching force on the ligaments of the said interphalangeal joint.
- 13. The dynamic tracion splint of Claim 12 wherein said means for biasing the two said phalanx-gripping means apart consists of a plurality of magnets and wherein:
 - a. said magnets are arranged to produce a magnetic repulsion force and
 - b. said magnets are attached to, or incorporated in, the two said phalanx-gripping means.
- 14. The dynamic traction splint of Claim 13 wherein said plurality of magnets consists of four magnets arranged as two pairs and wherein:

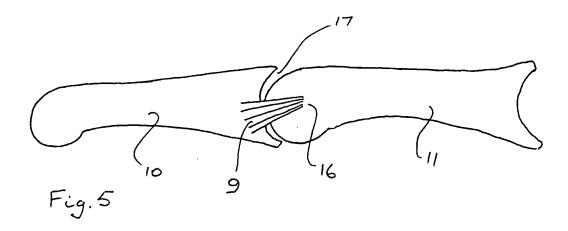
- a. one said pair is on each side of said digit and
- b. the respective magnets of said first phalanx-gripping means are positioned so their respective repellent magnetic poles are as close as possible to the axis of rotation of said interphalangeal joint thereby causing said magnetic repulsion force to be constant regardless of the degree of flexion of said interphalangeal joint.
- 15. The dynamic traction splint of Claim 13 wherein said plurality of magnets consists of six magnets arranged as two groups of three magnets each and wherein:
 - a. one said group is on each side of said digit,
 - b. said group is arranged as a pair of magnets spaced apart repelling one magnet thereby improving rotational stability of the two said phalanx-gripping means around said digit and
 - c. the magnet, or magnets, of said first phalanx-gripping means are positioned so their respective repellent magnetic poles are collectively as close as possible to the axis of rotation of said interphalangeal joint thereby causing said magnetic repulsion force to be constant regardless of the degree of flexion of said interphalangeal joint.
- 16. The dynamic traction splint of Claim 12 wherein said means for biasing the two said phalanx-gripping means apart consists of two compressed springs and wherein:
 - a. said springs are pivotally and removably attached on each side of the two said phalanx-gripping means and
 - b. said spring attachments to said first phalanx-gripping means are as close as possible to the axis of rotation of said interphalangeal joint thereby causing said biasing force to be constant regardless of the degree of flexion of said interphalangeal joint.

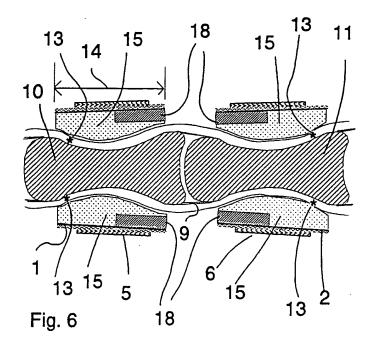
- 17. A method for treating osteoarthritis of an interphalangeal joint of a digit comprising the steps of:
 - a. applying a predetermined traction force to the collateral ligaments of said interphalangeal joint with the dynamic taction splint of any of the Claims 1 to 16,
 - b. applying said traction force for an interval of between five minutes and twelve hours,
 - c. vigorously flexing and extending said interphalangeal joint for a period of at least five minutes after said interval,
 - d. removing said dynamic traction splint and
 - e. repeating said treatment steps on a regular basis until symptoms of joint pain and stiffness are improved.

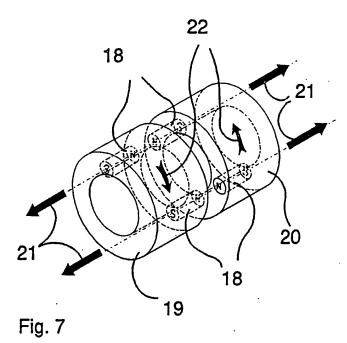
AMENDED SHEET (ARTICLE 19)











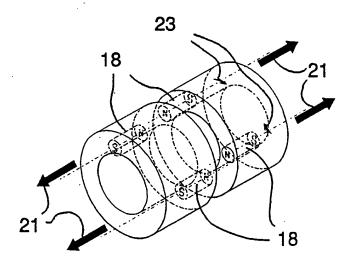


Fig. 8

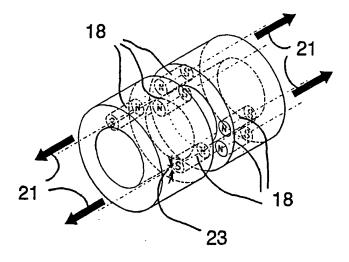


Fig. 9

(continuation)

The international application does not comply with the requirements of unity of invention because it does not relate to one invention or to a group of inventions so linked as to form a general inventive concept. The international searching authority has come to the conclusion that there are 3 inventions:

- 1. Claims 1-10, 12-16 are directed to a dynamic traction splint including means to grip first and second phalanx such that there is no torniquet effect on blood circulation and also a means for applying a stretching force on the ligaments of the interphalangeal joint.
- Claim 11 is directed merely to a phalanx-gripping means not a dynamic traction splint.
- 3. Claim 17 is directed to a method of treating osteoarthritis. The claim defines a traction being applied to an interphalangeal joint by a dynamic traction splint. However it is not limited to the splint as claimed in 1-1-, 12-16 as it does not include any of the distinctive technical features of the splint as defined by these claims.

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

	Patent Document Cited in Search Report			Patent Family Member	
us	4441489	GB	2094152		· · · · · · · · · · · · · · · · · · ·
EP	503182	CA	2043267		
US	4220334				
US	5020524				
	,				
				·	
				•	END OF ANNEX

This international search report has not established in respect of certain claims under Article 17(2)(a) for the following reasons: 1. Claims Nos.:
2. Claim Nos.: because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically: 3. Claims Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a). Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet) This International Searching Authority found multiple inventions in this international application, as follows: 1. Claims 1-10, 12-16 Dynamic traction splint with phalanx-gripping means such that it applies a stretching force on the ligaments of interphalangeal joint. 2. Claim 11 Phalanx gripping means.
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically: Claims Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a). Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet) This International Searching Authority found multiple inventions in this international application, as follows: Claims 1-10, 12-16 Dynamic traction splint with phalanx-gripping means such that it applies a stretching force on the ligaments of interphalangeal joint. Claim 11 Phalanx gripping means.
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a). Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet) This International Searching Authority found multiple inventions in this international application, as follows: 1. Claims 1-10, 12-16 Dynamic traction splint with phalanx-gripping means such that it applies a stretching force on the ligaments of interphalangeal joint. 2. Claim 11 Phalanx gripping means.
This International Searching Authority found multiple inventions in this international application, as follows: 1. Claims 1-10, 12-16 Dynamic traction splint with phalanx-gripping means such that it applies a stretching force on the ligaments of interphalangeal joint. 2. Claim 11 Phalanx gripping means.
 Claims 1-10, 12-16 Dynamic traction splint with phalanx-gripping means such that it applies a stretching force on the ligaments of interphalangeal joint. Claim 11 Phalanx gripping means.
Dynamic traction splint with phalanx-gripping means such that it applies a stretching force on the ligaments of interphalangeal joint. 2. Claim 11 Phalanx gripping means.
2. <u>Claim 11</u> Phalanx gripping means.
Phalanx gripping means.
Method for treating osteoarthritis of interphalangeal joint.
(For reasoning see extra sheet)
1. As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims
As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
Remark on Protest
The additional search fees were accompanied by the applicant's protest.
No protest accompanied the payment of additional search fees.
rm PCT/ISA/210 (continuation of first sheet(1))(July 1992) copjhw

A. CLASSIFICATION OF SUBJECT MATTER Int. Cl.⁵ A61F 5/10 According to International Patent Classification (IPC) or to both national classification and IPC B. FIELDS SEARCHED Minimum documentation searched (classification system followed by classification symbols) IPC A61F 5/10, 5/04 Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched AU: IPC as above Electronic data base consulted during the international search (name of data base, and where practicable, search terms used) DERWENT **JAPIO** C. DOCUMENTS CONSIDERED TO BE RELEVANT Category' Citation of document, with indication, where appropriate, of the relevant passages Relevant to Claim No. US, A 5020524, (DONOHUE) 4 June 1991 (4.06.91) X Col. 1 line 63 - Col. 2 line 64 17 A See whole document 1-16 EP,A, 503182 (DONOHUE) 16 September 1992 (16.09.92) X Col. 1 line 16-37 17 Α See whole document 1-16 US,A, 4220334 (KANAMOTO) 2 September 1980 (2.09.80) A Col. 2 lines 4-18 1-11, 13-17 US,A, 4441489 (EVANS et al) 10 April 1984 (10.04.84) A See col 1 lines 43-62 1-11, 13-17 X See patent family annex. X Further documents are listed in the continuation of Box C. later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention document of particular relevance; the claimed Special categories of cited documents: "T" document defining the general state of the art which is not considered to be of particular relevance earlier document but published on or after the international filing date "A" "E" "X" invention cannot be considered novel or cannot be considered to involve an inventive step when the document referring to an oral disclosure, use, exhibition or other means document published prior to the international filing date but later than the priority date claimed "L" document is taken alone document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such "O" "P" combination being obvious to a person skilled in "&" document member of the same patent family Date of the actual completion of the international search Date of mailing of the international search report 27 April 1994 (27.04.94) Authorized officer Name and mailing address of the ISA/AU S. Thomas AUSTRALIAN INDUSTRIAL PROPERTY ORGANISATION PO BOX 200 WODEN ACT 2606 **AUSTRALIA** S. THOMAS Facsimile No. 06 2853929 Telephone No. (06) 2832454